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The Secretary  
Federal Communications Commission  
1919 M. Street N.W. Room 222  
Washington, DC 20554

In the Matter of ) ET-Docket No. 93-62  
) and in this docket pertaining to:  
Guidelines for Evaluating the Environmental ) - Report and Order FCC 96-326  
Effects of Radiofrequency Radiation ) - First Memorandum of Understanding  
Order FCC 96-487

**Ex Parte Comments Pertaining to ET-Docket 93-62 Regarding  
PETITIONS FOR RECONSIDERATION of Commission Rule & Order FCC 96-326,  
and First Memorandum of Opinion and Order FCC 96-487**

with original and 1 copy submitted to the Secretary of the Commission  
in accordance with 47 CFR Sections 1.1200 to 1.1216  
8th Ex Parte Submission

Dear Mr. Secretary,

Enclosed please find an original and 1 copy of a written ex parte submission pertaining to ET-Docket 93-62. Please assure these are put in the official record of this proceeding. The purpose of this submission is to list the titles of some exhibits which have already been submitted, and to make comments on some of these exhibits for the purpose of further supporting the claims and requests in the Ad-Hoc Association Petitions for Reconsideration of FCC 96-326 and FCC 96-487.

Thank you,



David Fichtenberg  
Ad-hoc Association of Parties Concerned About the Federal Communications Commission's  
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dated August 21, 1997

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I hereby certify copies have been delivered or mailed August 22, 1997 to:

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August 22, 1997

Before the  
**FEDERAL COMMUNICATIONS COMMISSION**

Washington, DC 20554

In the Matter of	)	ET-Docket No. 93-62
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To: The Commission

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August 21, 1997

Submitted by the Ad-hoc Association of Parties Concerned About the Federal Communications  
Commission's Radiofrequency Health and Safety Rules  
PO Box 7577  
Olympia, WA 98507-7577 Tel: (206) 722-8306

Dated August 21, 1997

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## Summary

All exhibits that have been submitted by the Ad-Hoc Association of Parties Concerned About Federal Communications Commission's Radiofrequency Health and Safety Rules ("Ad-Hoc Association") are listed here for the convenience of those reviewing the evidence supporting the claims and requests of the Ad-Hoc Association in its Petition for Reconsideration of the Commission Rule and Order FCC 96-326 ("R&O"). Thus, when reading any Ad-Hoc Association submittal indicating footnotes that also appear as exhibits herein can be easily verified for correctness.

This submission summarizes some of the key requests made in the Ad-Hoc Association Highlights of some key explicit requests in the Petition and requests implied

I. Petition requests unrelated to changing hazard threshold, safety factors, or power density exposure levels - ie.no change in numerical limits

1.1. RF exposure from Commission licensed facilities and mobile transmitters shall be kept "as low as reasonably achievable" ("ALARA").

The definition of ALARA in 10 CFR §20.1003 should apply; this pertains to Nuclear Regulatory Commission ("NRC") radiation protection provisions.

1.2. A RF health and safety program should exist which mitigates any increase in worker risk

(i) A precedent in NRC rules 10 CFR 20 Subpart B Radiation Protection Programs should be modified in accordance with the RF health and safety program elements and objectives reported to the Commission by the National Institute of Occupational Safety and Health ("NIOSH") and the Occupational Health and Safety Administration ("OSHA").

(ii) Partial body exposure limit protections from fixed base station transmitter exposure should be required in the RF health and safety program, and not only be limited, as now, to applying to exposure from hand-held phones or other mobile devices.

(iii) Averaging time needs to be based upon a few seconds (5 seconds) due to headaches, and other mental stress observed in workers exposed under 10 seconds to levels which meet the Commission's limit for 6 minute averages

1.3. Protections and limitations of protection provided by Commission rules should be specified by the Commission.

Include noting present criteria is only known to protect from general body overheating, and should state other effects (cancer) were reported at levels below the Commission hazard threshold, and these effects should be listed in Commission instructional bulletins including OET Bulletin 56 for the general public and OET Bulletin 65 for technical use.

1.4. No 'grandfathering' of facilities, rather all regulated facilities must be required to follow the same numerical limits, and other uniform critier, regardless of when a facility was issued a license.

1.5. The criteria for when an evaluation is required must be modified to assure that all out-of-compliance conditions shall be detected

(i) Assuring out-of-compliance, especially when tall transmitters are close to nearby multi-story buildings or buildings of higher elevation, and which thereby are closer to the typically higher power output from the horizontal beam, resulting in out-of-compliance exposures at upper floor levels.

(ii) Local jurisdictions should have the option of specifying licensed agencies approved by the Commission, and responsible for monitoring exposure in established geograhic areas within the local jurisdiction.

1.6. Exposure predictions should be based upon reasonable 'worst case' situations, and not on predicted average or 'typical' exposure.

This should include exposures due to reflections of RF signals from corner walls that are electrically reflective (e.g. homes with aluminum siding), and exposure to the eyes of those wearing metal eye glass frames which can act as recieving and transmitting antennas.

1.7. All areas accessible by the public should be not be exposed to irradiation exceeding whatever limits are in place for the category of "general public/uncontrolled." The recommendations made to the Commission in 1993 by the EPA put the burden on the transmitter operator to assure the public quickly passes through areas of high exposure near transmitters; in contrast, the

Commission's rule places the burden on the public, who may not be sufficiently aware or able to act appropriately to assure safety.

1.8. Measurement of exposure conditions should include transmission pattern and other factors which scientists believe may reasonably have an impact on biological or health effects of the public or workers.

1.9. Determine that local regulation of RF exposure limits effects the "operation" of wireless transmitters and so is not preempted in the Telecommunications Act of 1996.

## II. Requests for more stringent hazard thresholds, safety factors, or power density exposure levels

1.10 Reduce environmental exposures to 40% of present values associated with given internal rates of absorption of RF energy - based on a computer method found valid by the FCC.

1.11. Reduce the FCC hazard threshold to no more than 15% of its current value - based upon the accepted RF standard setting criteria of disruption of learned behavior and scientific papers acceptable for standard setting.

12. Determine that FCC exposures should be reduced to 5%, 1%, or even 0.1% of current standards. But if the Commission will not make limits this stringent, then use the evidence justifying it to require that the ALARA standard shall be met, as well as the other precautions requested above.

The balance of this submission focuses on review reports of adverse health effects and seeks to reconcile seemingly opposing scientific assessments.

Finally, a listing is provided of exhibits that have been provided by the Ad-Hoc Association, and may help in locating and using these exhibits.

Before the  
**FEDERAL COMMUNICATIONS COMMISSION**

Washington, DC 20554

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**Regarding**  
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with original and 1 copy submitted to the Secretary of the Commission  
in accordance with ex parte submission rules in 47 CFR Section 1.1200 to 1.1216

Submitted by the Ad-hoc Association of Parties Concerned About the Federal Communications  
Commission's Radiofrequency Health and Safety Rules, PO Box 7577, Olympia, WA 98507-7577

8th Ex Parte Submission

Dated August 21, 1997

**1. Introduction:**

**1.1 Appropriate submission of an ex parte presentation**

The Ad-hoc Association of Parties Concerned About the Federal Communications  
Commission's Radiofrequency ("RF") Health and Safety Rules ("the Ad-Hoc Association")  
understands

- (i) that a Federal Communications Commission ("Commission") "Sunshine Agenda" period per 47  
CFR Section 1.1202(f) and Section 1.1203 is not now in effect regarding ET-Docket 93-62;
- (ii) that administrative finality has not yet been decided upon concerning the Commission's  
responses to Petitions For Reconsideration that have been submitted in this proceeding; and that
- (iii) this proceeding permits ex parte presentations in accordance with 47 CFR §1.1200 to 1.1216,  
and in accordance with the April 8, 1993 Notice of Proposed Rule Making in ET-Docket 93-62,  
paragraph 30.



Accordingly, the Ad-Hoc Association is properly making this ex parte submission.

1.2. The primary purpose of this submission is:

(i) to provide a listing of selected exhibits included in the Ad-Hoc Association Petition of Reconsideration of the FCC Rule and Order 96-326 (the Petition) which pertains to FCC Rule and Order 96-326 ("R&O") and to provide a listing of selected exhibits sent thereafter by the Ad-Hoc Association to the Commission. These exhibits and comments herein also support the claim in the Ad-Hoc Association Petition for Reconsideration of FCC First Memorandum of Order and Opinion FCC 96-487 that the Commission's exposure criteria during the transition period is also not sufficiently protective.

(ii) to provide a listing highlighting some key Ad-Hoc Association request in the Petition

(iii) to comment on some exhibits which add further support to these requests

To the extent exhibits were not previously referenced in presentations to the Commission, these exhibits became available and understood after the last opportunity for filing in this matter, and in any event, they significantly provide support for changes needed for the public health and consideration of them is in the public interest.

In this way, the Ad-Hoc Association is opportunity for the Commission to review and pass upon the matters presented herein, and by so doing the Commission will have the opportunity of verifying claims which have been made and of considering any newly discovered evidence which support the requests in the Petition.

Should the Commission find it should make changes elsewhere in its rules based on the evidence herein, it is requested that it do so, and make any other modifications it finds to be just and proper to serve the public interest.

1.3 Exhibits pertain to the following submissions in this proceeding of the Ad-Hoc Association:

1st ex parte submission dated June 10, 1997 ("ex parte 1")

2nd ex parte submission dated June 30, 1997 ("ex parte 2")

3rd ex parte submission dated July 7, 1997 ("ex parte 3")

4th ex parte submission dated July 9, 1997 ("ex parte 4")

5th ex parte submission dated July 14, 1997 ("ex parte 5")

6th ex parte submission dated July 24, 1997 ("ex parte 6")

7th ex parte submission dated July 31, 1997 ("ex parte 7")

**2. Highlights of some key explicit requests in the Petition and requests implied**  
(also see Summary in ex parte 2)

**I. Petition requests unrelated to changing hazard threshold, safety factors, or power density exposure levels - ie.no change in numerical limits**

**1.1. RF exposure from Commission licensed facilities and mobile transmitters shall be kept "as low as reasonably achievable" ("ALARA").**

The definition of ALARA in 10 CFR §20.1003 should apply; this pertains to Nuclear Regulatory Commission ("NRC") radiation protection provisions. Also see the Petition at pg. 18,19. Also see ex parte 1, items 11., 11.1-11.4. Whenever the Ad-Hoc Association has mentioned ALARA "should" apply, it was intended that ALARA be required and thus "shall" apply.

**1.2. A RF health and safety program should exist which mitigates any increase in worker risk**

(i) A precedent in NRC rules 10 CFR 20 Subpart B Radiation Protection Programs should be modified in accordance with the RF health and safety program elements and objectives reported to the Commission by the National Institute of Occupational Safety and Health ("NIOSH") and the Occupational Health and Safety Administration ("OSHA"). See the Petition at pg. 17, 18, and details in ex parte 2, especially see ex parte 2 pages 48 to 60.

(ii) Partial body exposure limit protections from fixed base station transmitter exposure should be required in the RF health and safety program. Partial body protection from high localized RF exposure is addressed in FCC 96-326 only in §2.1091, for evaluating mobile and unlicensed devices. That the Ad-Hoc Association has requested that such protection be provided is clear from objections by the Ad-Hoc Association that the "Relaxation of Limits of Partial Body Exposure" in IEEE C95.1-1991 would violate the basic partial body specific absorption rate exposure protections the standard states it provides. [see Petition at item 14.9, pg. 13]

(iii) Averaging time needs to be based upon a few seconds (5 seconds) due to observed adverse effects in occupational settings and related experimental results [see ex parte 2, item 2.6 at pages 8 to 15, and see exhibit E18 below]. Note that Petition items 19., 19.1 to 19.3 at pages 15 and 16, include seeking exposure limits which would have the effect of helping to prevent the high exposures possible during a period of a few seconds under the Commission's limits in §1.1310. Also, see the Petition, exhibit 4 therein where letters dated April 1991, to IEEE from FDA scientists Dr. M. Swicord and Dr. M. Altman include note,

*"Little attention has been paid to the appropriate averaging time. The standard still uses 15 GHz for frequencies below 15 GHz. 6 minutes was arbitrarily chosen and has no significance in terms of thermal loading to cells or any other biological response."*

**1.3. Protections and limitations of protection provided by Commission rules should be specified by the Commission.**

Include noting present criteria is only known to protect from general body overheating, and should state other effects (cancer) were reported at levels below the Commission hazard threshold, and these effects should be listed in Commission instructional bulletins including OET Bulletin 56 for the general public and OET Bulletin 65 for technical use. See the Petition at pages 7, item 18 at pages 14, 15, item 20 at pg. 16. Also see ex parte 1 items 3 through 7.

**1.4. No 'grandfathering' of facilities, rather all regulated facilities must be required to follow the same numerical limits, and other uniform criteria, regardless of when a facility was issued a license.** Since there is knowledge that some presently authorized mobile transmitters and devices exceed safety limits, these must be re-authorized and recalled if out-of-compliance, and if not, then to have warnings issued to users. [see the Petition at item 13 and 14, see ex parte 1 item 14 at pages 46-48]. Also, the Ad-Hoc Association Petition For Reconsideration of FCC 96-487 states there should be no 'grandfathering' as defined by *"implementing the more stringent rules (as requested by the Ad-Hoc Association) without delay, and to recertify previously approved applications by these new rules."* [at page1]

47 CFR §1.1307(b)(1) states, "The exposure limits in §1.1310 are generally applicable to all facilities, operations and transmitters regulated by the Commission," and this must be strictly

followed by the Commission, with "generally applicable" meaning "always applicable." Whether the Commission adopts limits requested by the Ad-Hoc Association or otherwise, whatever limits will be in §1.1310 the Commission should require that upon the date of implementation of these limits that all facilities it regulates, regardless of when their license was issued, shall be required to be in compliance with these limits and other criteria included in the implementation.

Likewise, hand held devices must demonstrate compliance, since recent testing has found exempt devices have exceeded both past and to-be-implemented partial body exposure limits.

**1.5. The criteria for when an evaluation is required must be modified to assure that all out-of-compliance conditions shall be detected, and thus must consider horizontal proximity of accessible areas exposed to the facility, especially accessible areas horizontally close and near the same elevation as transmitters.**

(i) Assuring out-of-compliance, especially when tall transmitters are close to nearby multi-story buildings or buildings of higher elevation, and which thereby are closer to the typically higher power output from the horizontal beam, resulting in out-of-compliance exposures at upper floor levels.[see the Petition at pages 4, 5]

(ii) Local jurisdictions should have the option of specifying licensed agencies approved by the Commission, and responsible for monitoring exposure in established geographic areas within the local jurisdiction. Commission licensees would be required to coordinate monitoring reporting with such agency See petition at item 11, page 8.

**1.6. Exposure predictions should be based upon reasonable 'worst case' situations, and not on predicted average or 'typical' exposure.**

This should include exposures due to reflections of RF signals from corner walls that are electrically reflective (e.g. homes with aluminum siding), and exposure to the eyes of those wearing metal eye glass frames which can act as receiving and transmitting antennas. [See the Petition at item 12, page 8,9].

**1.7. All areas accessible by the public should be not be exposed to irradiation exceeding whatever limits are in place for the category of "general public/uncontrolled."**

Consider the 1986 RF standard of the National Council for Radiation Protection and Measurements referenced in the R&O. The Commission has stated that its rules seek to accomplish "the intent of the NCRP criteria." [R&O at para 42]. NCRP 17.4.3 states,

*"the 30 minute time-averaging period is responsive to some special circumstances for the public at large. Examples are transient passage by the individual past high-powered RFEM sources, and brief exposure to civil telecommunications systems."*

Yet for the very examples cited above by NCRP, the Commission, by §1.1310, in its Note 1 to Table 1, specifies that the members of the public may have to endure the typically 5 fold higher occupational/controlled exposures *"when an individual is transient through a location where occupational/controlled limits apply provided he or she is made aware of the potential for exposure."*

NCRP 17.4.3, however, does not allow these five fold higher limits, but rather to remain in compliance, the burden is placed upon the operator to assure that the public moves quickly through such areas, as intended by NCRP, so that for any 30 minute period the average exposure will not exceed that set for the general population/uncontrolled limits.

Instead, by its present rule in the R&O, the Commission transfers the burden from the operator (as under the NCRP 17.4.3 rule) and instead is putting the burden on the general public to of its own accord move out of an area where people may be transient. EPA has strongly opposed relying on the public being made "aware" of the exposure. It is possible that this may be taken to apply to such public areas where people are transient as: an airport, or perhaps shopping malls, or other places where there are both workers and the public. Also children may play near work areas. It is essential that the burden be on the operator to assure rapid movement through areas with exposures that exceed those for the general population - otherwise, this may 'open the door' to many public areas in fact being 'legally' exposed to irradiation levels with limits five fold higher.. [see Petition at item 21, pg. 16]

**1.8. Measurement of exposure conditions should include transmission pattern and other factors which scientists believe may reasonably have an impact on biological or health effects of the public or workers.**

This information will be needed to subsequently evaluate if there are health impacts to workers or the public from certain transmission patterns. While the Commission has decided there is not sufficient information to establish exposure limits based upon transmission patterns, this does not preclude only reporting what these transmission patterns are; indeed, such reporting is justified given concern for this matter in the scientific and standard setting communities. See the Petition at item 12, page 8, 9. Also see National Council for Radiation Protection and Measurements Report #86 section 17.4.7 for a rationale of why these patterns should at least be reported. Also see Exhibit E182 where Commission staff and leading scientists identify and recommend parameters, including transmission patterns, which may influence health and thus should be reported in order to later determine if they cause effects.

**1.9. Determine that local regulation of RF exposure limits effects the "operation" of wireless transmitters and so is not preempted in the Telecommunications Act of 1996.**

The Commission must correct the statement it made in its R&O that the Telecommunications Act of 1996 provides for,

*"federal preemption of state and local regulation of personal wireless services facilities on the basis of RF environmental effects." [R&O 166]*

While the Commission indicated in a footnote (#202) that this preemption is restricted only to the functions of *"placement, construction, or modification"* it did not do so in the text of its R&O, and this may mislead some states and local jurisdictions to understand that regulating the operation of such facilities is also preempted. In particular, regulating the allowed RF exposure during the ongoing "operation" of these facilities is clearly not part of the preempted functions, since regulation of such operations occurs well after the placement, construction, or modification of a facility. [See the Petition at item 15 at page 13-14; also see the "Comments on, some statements in support of, and some statements in opposition to some requests in petitions for reconsideration" of David Fichtenberg filed October 8, 1996 in this proceeding, see pages 13 to 17 therein.]

**II. Requests for more stringent hazard thresholds, safety factors, or power density exposure levels**

1.10 Reduce environmental exposures to 40% of present values associated with given internal rates of absorption of RF energy - based on a computer method found valid by the FCC.

[see Petition at pg. 14, see Ad-Hoc Association FCC96-487 petition at 2.13 page 8-11, see Ad-Hoc Association Reply comments dated October 28, 1996 at item 4, ex parte 1, item 16 pg.49-52]

1.11. Reduce the FCC hazard threshold to no more than 15% of its current value - based upon the accepted RF standard setting criteria of disruption of learned behavior and scientific papers acceptable for standard setting.

[see the Petition at pages 9-12, pages 15-16; see above October 28, 1996 reply comments at item 3, ex parte 1, pages 19-22, item 15 pages 48-49; see ex parte 2 item 25]

1.12. Determine that FCC exposures should be reduced to 5%, 1%, or even 0.1% of current standards. But if the Commission will not make limits this stringent, then use the evidence justifying it to require that the ALARA standard shall be met as well as the other precautions requested above.

[see the Petition at items 4., 4.1-4.5 at pages 4,5 and items 19., 19.1-19.3 at pages 15,16, and see extensive justifications in ex parte 1 through this submission.]

2. The word 'guidelines' when referring to the Commission criteria should be changed everywhere to "requirements," since a guideline is presumed only advisory, and given the evidence in the record any RF exposure standard to protect the public and workers must have criteria that shall be met.

For example, R&O para160 should be,

"The Commission ~~requires that expects~~ all its licensees ~~shall~~ to comply with the RF ~~guidelines requirements~~ specified in our rules, ~~or, if not, to file an Environmental Assessment for review under our NEPA procedures.~~"

Also, 47 CFR §1.1310 (b)(1) should be,

"The exposure limits in §1.1310 ~~shall be~~ ~~are generally~~ applicable to all facilities and transmitters regulated by the Commission."

Likewise, §1.1310 (b)(3) should be:

*"~~In general, when the requirements-guidelines~~ specified in §1.1310 are exceeded in an accessible area that receives ~~due to the emissions from multiple fixed transmitters, actions necessary to bring the area into compliance with the requirements shall be~~ ~~guidelines are the~~ ~~shared responsibility of all licensees whose transmitters produce field strengths or power density levels at the area in question in excess of 1% of the exposure limits applicable to their particular transmitter.~~"*

The above is a clarification of previous Ad-Hoc Commission requests, and throughout the R&O reference should be made to required limits and criteria which shall be met. This is the intent of all of the requests of the Ad-Hoc Association, e.g. whenever it may have been suggested or implied that exposures *should* be kept as low as reasonably achievable, it is intended the Commission require that exposure *shall* be kept as low as reasonably achievable.

### 3. Comments on Exhibits

The main focus of all of the comments that follow is to stress that there is evidence pointing to a portent of adverse effects at exposure levels below the hazard threshold upon which the Commission's limits are derived.

Moreover, by so discussing these exhibits it will assist the federal health agencies or others with expertise in RF health issues and from whom it is expected the Commission will seek assistance.0

E1 (Exhibit #1) appendix reviews EPA analyses of a 25 month University of Washington study, E5, and reports additional findings of tumors not reported in the peer-reviewed article: benign pheochromocytoma of the adrenal medula ( $p < 0.023$ , one tailed), malignant tumors at all sites ( $p < 0.0012$ ), carcinomas at all sites ( $p < 0.018$ ) and glandular carcinoma for combined glands ( $p < 0.018$ ). ( $p < x$  means the likelihood of seeing this difference or more is less than  $x$ ).

E2 shows immune system sensitivity at 0.015 W/kg, 30 microwatts per sq. cm. at 2450 MHz.

Noted in footnote 14 of the Petition



**E3** shows potential mutagenic effect for mice exposed to average whole body SAR of 1.18 W/kg.  
**E4** shows results of study of rodents maintained less hygienic conditions than for the University of Washington experiment, in E5 and E6, and where E5 compares results to those in E4.

**E5** shows greater hygienic conditions than in E4, to which this experiment is compared.

Referenced at P: footnote 27. Shows greater than 3 fold risk of primary malignancy in RF exposed rats.

**E6:** shows the experimental design for E5, useful for details on hygienic conditions, and also for noting that the original plan did not indicate an intention to measure disruption of a learned behavior or learning of a new behavior even though such measure had been considered the most sensitive RF adverse health effect.

**E12** Shows adverse effects at low RF exposures; it also shows that when American researchers carefully replicated a Soviet study that they got the same results. Here, this included an adverse effects, including behavior disruption, at 500 microwatts per sq. cm on rats

**E188** reports an increased incidence of cancer was found among persons living in census tracts that had TV or radio broadcast towers in Honolulu, Hawaii

**E189** indicates the potential for electric and telephone wiring and/or metal plumbing in homes or offices to act as RF antennas.

**E191:** The author reviews 7 epidemiology studies of RF radiation and cancer in adults. The review is helpful by at least identifying what the author considers as the relevant studies on this subject. Of these 7 studies, 5 are reported as showing statistically significant increases in some types of cancer in the report (4 in this review: 1- Milham a, 2- Milham b, 3- Hawaii at Exhibit 188, 4- Robinette herein and at Exhibit 89 where respiratory cancer and total mortality rate are reported as significant. 5- Szmigelski, 1996, Exhibit E49 showed many statistically increased cancer incidence rates in the exposed population. 6- showed trends of increased cancer (but was not statistically significant perhaps due to small sample sizes (6-Hill), and a study (7- Lillienfeld et al at Exhibit 144) of the U.S. Moscow Embassy and other Eastern European embassies was found

to have higher RF exposure than typical in the United States and also both had higher cancer rates in comparison to deaths for other causes. Exhibits E39 and E178 discuss many of the above studies and show how they are consistent with an RF - cancer link. It is unclear why the author of this study suggests the statistically significant increase in total mortality and respiratory cancer may be "fortuitous" since the source article (at Exhibit 89) showed increased cancer mortality trends (not statistically significant) in all listed cancer categories except one (with the smallest number of occurrences). Also, observation of the rates for each group cause of death shows that the total death rate is statistically significant for the exposed group due to a general tendency for the death rates to be higher for the exposed group for most cause of death categories - but not statistically significant, probably due to small sample sizes.

Thus, all 7 RF - cancer studies reported either show a statistically significant adverse effect or show trends consistent with an adverse cancer effect, although not statistically significant.

**E192:** Potential Public Health Risks From Wireless Technology: Research Agenda for the Development of Data for Science-Based Decisionmaking ("Potential Health Risks"), 1994 is a report prepared by the Scientific Advisory Group on Cellular Telephone Research ("SAG"), which was commissioned to manage a research program and that, *"Industry support for the research initiative is coordinated through the Cellular Telecommunications Industry Association (CTIA)."* [see footnote 1 on page i of Potential Health Risks]. Among some of the noteworthy points in this report are:

1. Some of the techniques for digital-type modulations *"can introduce amplitude modulate"* (with a footnote 22 that amplitude modulation *"has raised questions relating to reported amplitude modulation and pulse modulation frequency window effects that will be addressed in the research plan."* [page 45] ).

2. *"there is some evidence, though not widely accepted, that weak fields modulated at certain frequencies or with high peak power pulses can produce biological effects."* [page 47]

The above acknowledgments of observed modulation effects and of *"some evidence"* of biological effects from weak modulated fields supports the Ad-Hoc Association claims that the Commission cannot know its limits are sufficient to protect the public health from adverse effects

other than thermal heating. Hence, it also supports the petition request that RF exposure "shall be kept as low as reasonably achievable." Also note that given the evidence presented by the Ad-Hoc Association and others in this proceeding for potential adverse effects at exposure levels below the Commission's limits, it should be understood that whenever in this proceeding the Ad-Hoc Association states a criteria "should" apply, it means that the Commission's rule should state the criteria "shall" apply.

3. Section 6.0 "Principles Guiding the Research Program" notes *"Currently, there are few data relevant to health risk from exposure to 824-849 MHz."* [page 115 of report E192]. It also states, *"In the near future, newer technology will be using 1800-2200 MHz with complex modulations, and this should be investigated as well so advances in technology do not render the health database partially obsolete shortly after the cancer evaluation is complete."* [page 115 of report E192].

4. Appendix 5 of E192 provides a 1993 review "Microwaves and Cancer- A Summary Prepared By the Radiation Biology Branch, Center For Device and Radiological Health, the U.S. Food and Drug Administration ("FDA"). Also reviewed on page 73 of E192. The review concludes,

*"The fact remains, however, that the data which exists strongly suggests that microwaves can, under at least some conditions, accelerate the development of malignant tumors. This in vivo data is also supported by in vitro data which has demonstrated not only malignant transformation but other effects on the cell's growth control mechanisms."* [Appendix 5 of E192].

The FDA also notes,

*"The only study reported in the peer-reviewed literature that did not show accelerated tumor progression [(Santini, 1988)<sup>1</sup>] used mice with melanomas subcutaneously implanted under their skin. Exposure to 2450 MHz microwaves (both unmodulated and pulsed) for 2.5 hours a day did not affect tumor progression or survival times. One reason that this study may have given a negative result is that the mice only lived about 6 weeks after implantation of the highly malignant melanoma cells, dying of the effects of the tumor. The Szmigelski data shows that*

*about 4 months of exposure is necessary before tumor progression is accelerated by microwaves. The melanoma implanted mice thus did not survive long enough for their disease to be accelerated by the microwave exposure."* [Appendix 5 of E192].

5. Section 5.4.3 of E192, Animal Cancer Studies, provides evidence that the review of studies by the Ad-Hoc Association is reasonably complete [in Ex Parte Comments of June 10, 1997, pg 24-29]. It also shows that animal cancer studies discussed in the 1993 World Health Organization report, see E203, is reasonably complete as is the review by the U.S. Food and Drug Administration noted in E192- point 4 above. When discussing E192 Section 5.4.3, it is also helpful to consider that in the 1993 World Health Organization report, see E203, it notes that

*"Exposures to RF levels sufficiently high to induce hyperthermia has generally resulted in tumour regression following transplantation of tumour cells. In contrast, an increase in tumour progression has been observed in mice exposed long-term at lower, possibly thermogenic, SARs. [Section. 7.3.10 and 7.3.11, pages 148-154, of WHO, 1993, pg. 148- and given in Exhibit 203]<sup>2</sup>.*

#### **Comments on the "negative" studies**

A review of the animal cancer studies noted in E192 section 5.4.3 shows that the studies not finding a positive association between RF and malignancy are either:

(1) studies likely to cause hyperthermia (as noted above in the WHO 1993 report page. 148) and includes: Preskorn et al (1978), with exposure at 35 W/kg [from E192, pg. 96], Roszkowski et al,(1980) with exposure at 25 W/kg [pg. 149 WHO, 1993]], and Wu et al. (1980) [see Exhibit 10, with exposures 10 to 12 W/kg].

(2) studies less than 4 months duration which the FDA notes above may lack insufficient time for the RF/Microwave effects to become apparent. "negative" studies of this type listed in E192 Section 5.4.3 include: Santini (1988) with exposures lasting about 6 weeks or so [see above FDA comment in Appendix 5 of E192], Salford et al. (1993) in which rats were reported to be exposed to RF from 2 to 3 weeks which was reported to last from 2 to 3 weeks [the results report RF treatments of 7 hours per day, 5 days per week, with a maximum of 15 treatments i.e. 3 weeks exposure - see page 315 of E8]. Moreover, even the "negative" studies by Santini (1988) and

Salford (1993) showed some results consistent with a positive association. For mice exposed for the longest period in the Santini study, those exposed to pulsed RF had tumors 30% larger than controls. Similarly Salford et al. noted that when there was a big difference in tumor size it was typically the RF exposed rat who had the larger tumour [see Ex Parte Comments #2 dated June 30, 1997, item 7.10 and 7.11 on pages 27-28]. Thus, even these "negative" studies show some positive indications (but, reportedly not statistically significant) of RF accelerating tumor development.

Thus, all of the "negative" animal cancer studies reported in E192 either had high RF exposure (10 W/kg or higher) likely causing heating of the animal, or were of short duration (less than 2 months) limiting the possibility of seeing a long-term RF effect. Yet, even among these there were signs of positive association, although reportedly not statistically significant.

#### **Comments on the "positive" studies**

E192 lists 7 studies finding a positive association between RF exposure of about 4 W/kg or less [these are studies in items 7.3 to 7.3, page 25-27 of the June 10 1997 ex parte comments of the Ad-Hoc Association, and are respectively in the June 10, 1997 ex parte comments those by Chou (1992), Szudzinski (1982), and 5 by Szmigelski (1982). These studies are also referenced in Appendix 5 of E192, which is the 1993 review of the FDA noted above. Also, it is noteworthy that the 1982 Szmigelski paper was found by the scientific committees of the IEEE to meet the high standards for quality scientific design, dosimetry, and analysis to be included in the Final List of Papers Reviewed For IEEE C95.1-1991, the IEEE RF standard.

Yet, in contrast to the assessments of the FDA and 1991 IEEE committees noted above, the 3 authors of E192 questioned the positive associations of RF with malignancy found in the above papers. The reasons for these authors' criticisms are unclear. This is because:

For the Szmigelski 1982 studies:

1. Szmigelski estimates average whole body exposure to be 2 to 3 W/kg. In a subsequent review, assuming the mice are in the E position as often as in the H position to the incoming RF exposure, Guy (1995)<sup>3</sup> estimates the average whole body average Specific Absorption Rate of RF energy at 4.1 W/kg. In any case, since the Commission's exposure limits are based upon a hazard

threshold of 4 W/kg, the Szmigelski studies raise reasonable doubts about the validity of this hazard threshold value, since the Commission's hazard threshold of 4 W/kg is above or about equal to the 2 W/kg to 4.1 W/kg at which Szmigelski et al. 1982 found significant increases in the acceleration of malignant tumors at this exposure level [as noted in the ex parte comments of the Ad-Hoc Association dated June 10, 1997, pages 25-27].

The 3 E192 authors note that the study showed that confinement stress reduced the latent period for spontaneous sarcoma cells in a manner similar to exposure to 5 mW/sq. cm, and then conclude this result is *"suggesting that the nature of animal housing may have been an important confounding factor in this study."* [E192 pg. 99] It is unclear why the authors suggest this since the RF exposed and sham exposed mice were kept in identical living conditions, for the same length of time, and in cages of the same size, thereby addressing any potential confounding 'confinement' effect. Studying 'confinement stress' by putting one group in smaller cages was a separate sub-study, any effects of confinement, while interesting, do not detract from the comparison between the RF exposed and sham exposed animals kept under the same living conditions.

Also, the 3 authors of E192 state with respect to the application of a skin carcinogen 3,4, benzopyrene (BP), *"nor was there any reported increase progression of tumors to a more advanced stage."* [page 100]. It is not clear why this comment is made since the paper groups the mice with the three most advanced stages of cancer into a single group designated as those with skin cancer (or equivalently with "tumors") vs. early stages which were considered as "skin lesions." Therefore Szmigelski et al. (1982) does differentiate between skin cancer and precancerous skin lesions and does include the 3 most advanced stages as one category. Furthermore, for example, when mice with tumors in the 3 most advanced stages are compared at 8 months, significant differences are found. Specifically, when sham-irradiated mice treated for 5 months with BP were compared to mice irradiated with RF while also being similarly treated with BP, after 8 months from the start of treatment only 3 of 40 sham irradiated mice had tumors in the 3 highest advanced stages, whereas 18 of 40 mice irradiated at the lower dose estimated at 2 to 4.1 W/kg had tumors in the 3 highest advanced stages. Similar results were found for other of the

Szmigielski experiments [see ex parte comments of June 10, pages 25-27]. Moreover, the purpose of the Szmigielski et al. studies was not to study in detail the rate of progression from no lesion to each stage of precancerous and cancerous lesions, but rather with only a sample of 40 mice per condition to study when mice develop skin cancer. The authors state they chose a 7 grade scale with scores 0 to 6, with the advanced stages 4, 5, and 6 designated as skin cancer, and stages 1,2, 3 as precancerous lesions. As the mice were only checked every 2 weeks, it was not possible to identify the specific point at which stage 4 cancer began; hence all of the advanced stages 4 to 6 were grouped into one category. For these reasons it is unclear why the 3 authors of E192 stated, "*nor was there any reported increase progression of tumors to a more advanced stage.*" [page 100]. The E192 authors also report that a "0-7 scale" was used, but the authors of the paper report a 7 grade scale of 0 to 6.

Also, the E192 authors report, "there was no apparent progression of tumors to more malignant forms with RFR treatment." [pg. 100]. It is unclear why this is noted since the advanced stages from 0 to 6 (there was no "7") were all grouped into one category, and consequently progression from skin cancer at stage 4 to 6 was not a subject which was even addressed in the paper.

The 3 authors of the E192 report also make comments on exposure at the higher level, with average whole body SAR estimated at 6 to 8 W/kg by WHO 1993<sup>2</sup> and by Szmigielski et al (1982), and 12.3 W/kg by Guy (1995)<sup>3</sup>. However, since our concern is the appropriateness of the 4 W/kg hazard threshold, outcomes at this higher exposure do not seem relevant here.

Thus, while it is true that any housing condition, handling, or other protocol may stress the animals, by having a sham irradiated control these other factors are balanced so confounding will not occur. Therefore, since the RF irradiated mice and sham irradiated mice were otherwise treated the same, since lesions were categorized into precancerous and cancerous, and since the differences in acceleration of tumor development was dramatic [see June 10, 1997 ex parte comments of the Ad-Hoc Association, pages 25-27], it is not clear why the 3 authors of E192 state,

*"the implied conclusions of the authors that RFR treatment alone resulted in an acceleration in tumor development cannot be substantiated from the reported results," and that "the conclusion of the authors that RFR may be recognized as a carcinogenic risk factor is not supported by the data presented."* [E192, page 100].

Considering the above different views, the Commission is reminded that it has stated that its policy is to defer to the expertise of the federal health agencies participating in this proceeding. Therefore, please recall the above FDA quote in which it reviewed the Szmigielski et al. 1982 studies and stated, *"The Szmigielski data shows that about 4 months of exposure is necessary before tumor progression is accelerated by microwaves."* [Appendix 5, E192].

Moreover, the Commission is reminded that these studies by Szmigielski et al. (1982) were among the Final List of Papers Reviewed for IEEE C95.1-1991. In that standard it states, *"Only those papers with adequate dosimetry were judged acceptable. The relevance of each of these reports to standard setting was evaluated, as were the scientific quality and originality of the data, reliability, and evidence of adverse effects. The evaluation stressed thresholds of adverse effects and the extent to which the findings had been verified in independent investigations. Reports embodying questionable statistical methods were evaluated further by a Statistical Evaluation Working Group."* [IEEE C95.1-1991, Section 6.4 Assessment Criteria, pg. 26-28].

Thus, both the FDA and the RF 1991 IEEE committees found the Szmigielski et al. 1982 paper of high quality, well designed, measured, and evaluated. It therefore, seems the 3 authors of E192 may have overlooked or misunderstood certain important aspects of this paper, resulting in their view being opposite that of the FDA and the findings of the RF 1991 IEEE committees reviewing adequacy of scientific quality of papers. Since the Commission has stated it defers to the advice of the federal health agencies, such as FDA, it is further expected that the Commission will view this paper in accordance with the FDA assessments given above.

Concerning replication, E192 correctly states that the paper by Szudzinski et al. 1982 [see Exhibit E7, included with ex parte comments dated July 14, 1997] was essentially a replication of the Szmigielski et al. 1982 results when mice were simultaneously treated with BP and exposed to



the same RF conditions as Szmigielski except there were 100 mice in each treatment group. This study, also referenced by the FDA review above further establishes the validity of the Szmigielski et al. 1982 findings.

The other animal cancer paper discussed at length in E192 is that of Chou et al (1992) provided in Exhibit E6 [submitted with ex parte comments dated July 14, 1997]. For Ad-Hoc Association comments on this study please see the Ad-Hoc Association FCC 96-326 Petition at page 16, item 19.3, footnote 111 therein, and also see ex parte comments dated June 30, 1997, item 7.2 pages 43-45. The authors of E192 state the more than 3 fold increase of primary malignant tumors (18 of 100 for exposed vs. 5 of 100 for non-exposed) "is of doubtful biological significance." [at E192, pg. 102]. From the discussion there it can be seen: the E192 authors note (1) other studies of similarly aged animals showed similar incidences; but this is supported in E5 (Chou et al. 1992) by referring to E4 (Anver et al. 1982) which did not have the special pathogen free environment as in E5 discussed here.]. (2) E192 also notes that the malignant tumors arose in sites with no benign counterparts; but, it would seem that this unusual pattern would serve to support that RF had an effect, since it resulted in a tumor pattern different from the "historical control" that Chou et al (1992), in E5, referenced as E4 (Anver, 1982). (3) Finally, E192 and E5 note that there was no statistically significant increase of tumors at any single site; but Appendix 5 of E192 in the report by the FDA states, *"this is precisely what one would expect for an agent which accelerates the progression of naturally occurring malignant cells."* Similarly, the U.S. EPA has made the scientific judgment that such results are evidence of cancer, being the minimum required, as the EPA reports,

"A statistically significant excess of tumors of all types in the aggregate, in the absence of a statistically significant increase of any individual type, should be regarded as minimal evidence of carcinogenic action unless there are persuasive reasons to the contrary." [Federal Register Vol. 51, No. 185, pg. 33995, see Exhibit E65].

Moreover, in a review of an EPA report, the Nonionizing Electric and Magnetic Fields Subcommittee of the (EPA) Science Advisory Board's Radiation Advisory Committee (see Exhibit #1, i.e. E1, EPA-SAB-RAC-92-013, January 29, 1992) the Appendix B reviews an EPA